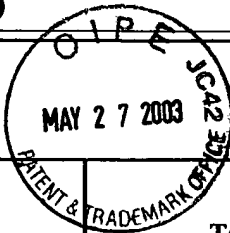


Change Of Attorney Or Agent's Address In Application
(37 CFR 1.8(a))

Docket No.

C35795/125237

In Re Application Of: Jerome CANTOR, et al.



Serial No.
09/863,849

Filing Date
May 23, 2001

Examiner
To be Assigned

Group Art Unit
1623

Invention: METHOD FOR THE PREVENTION OF TISSUE ELASTIC FIBER INJURY

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Please send all correspondence for this application to:

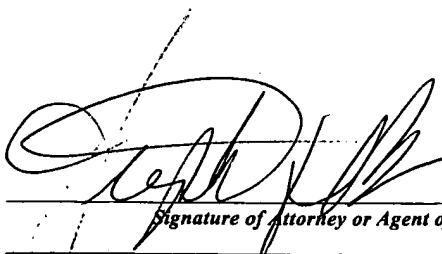
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104

Phone: 212-541-2000
Fax: 212-541-4630

RECEIVED
MAY 28 2003
TECH CENTER 1600/2900

Please direct all telephone calls to:

Stephen J. Brown

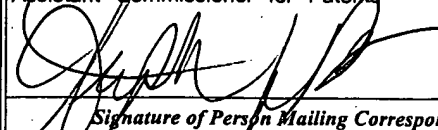

Reg. No. 43,519
Signature of Attorney or Agent of Record

Dated: May 22, 2003

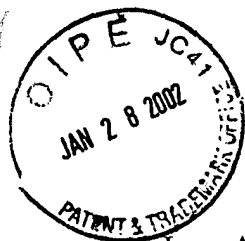
Stephen J. Brown
Reg. No. 43,519
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104

Registration Number & Address of Attorney or Agent of Record

I certify that this document is being deposited on
May 22, 2003 with the U.S. Postal Service as first
class mail under 37 C.F.R. 1.8 and is addressed to the
Assistant Commissioner for Patents


Signature of Person Mailing Correspondence

Stephen J. Brown
Typed or Printed Name of Person Mailing Correspondence



Docket No.: C35795/125237

1623
#5
MW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Jerome CANTOR, et al.) Examiner: To be Assigned
Serial No.: 09/863,849) Group Art Unit: 1623
Filed: May 23, 2001)

RECEIVED
JAN 31 2002
TECH CENTER 1600/2900

For: METHOD FOR TREATING RESPIRATORY DISORDERS
ASSOCIATED WITH PULMONARY ELASTIC FIBER INJURY

December 17, 2001

INFORMATION DISCLOSURE STATEMENT

Box DD
Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants wish to make of record the below listed documents. Document nos. 10-25 are enclosed, and document nos. 1-9 and 26-78 were supplied in Parent Application Serial No. 09/079,209 in Information Disclosure Statements filed August 14, 1998, September 2, 1999 and November 13, 2000. A copy of the PTO-1449 Forms returned and initialed by the Examiner are enclosed. In accordance with 37 C.F.R. §1.98(d), copies of reference nos. 1-9 and 26-78 which were previously submitted in the parent application are not required.

U.S. Patent Documents

| | <u>Patent No.</u> | <u>Issue Date</u> | <u>Inventor</u> |
|----|-------------------|-------------------|-----------------|
| 1. | 5,663,003 | May 27, 1998 | Cantor |
| 2. | 5,872,109 | Feb. 16, 1999 | Akima, et al. |

| | | | |
|-----|-----------|---------------|---------------------|
| 3. | 5,990,096 | Nov. 23, 1999 | Asculai, et al. |
| 4. | 5,993,783 | Nov. 30, 1999 | Eljamal, et al. |
| 5. | 5,929,048 | Jul. 27, 1999 | Falk, et al. |
| 6. | 5,707,604 | Jan. 13, 1998 | Ranney |
| 7. | 5,767,106 | Jun. 16, 1998 | Turley, et al. |
| 8. | 4,925,678 | May 15, 1990 | Ranney |
| 9. | 4,725,585 | Feb. 16, 1988 | Wenge, et al. |
| 10. | 5,690,961 | Nov. 25, 1997 | Nguyen |
| 11. | 5,679,657 | Oct. 21, 1997 | Oka, et al. |
| 12. | 5,356,883 | Oct. 18, 1994 | Kuo, et al. |
| 13. | 4,605,691 | Aug. 12, 1986 | Balazs, et al. |
| 14. | 4,863,907 | Sep. 5, 1989 | Sakurai, et al. |
| 15. | 4,716,224 | Dec. 29, 1987 | Sakurai, et al. |
| 16. | 5,532,221 | Jul. 2, 1996 | Huang, et al. |
| 17. | 5,652,347 | Jul. 29, 1997 | Pouyani, et al. |
| 18. | 5,783,691 | Jul. 21, 1998 | Mälson, et al. |
| 19. | 4,965,353 | Oct. 23, 1990 | della Valle, et al. |
| 20. | 5,336,767 | Aug. 9, 1994 | della Valle, et al. |
| 21. | 5,202,431 | Apr. 13, 1993 | della Valle, et al. |
| 22. | 5,017,901 | May 21, 1991 | Yoshimura |
| 23. | 6,027,741 | Feb. 22, 2000 | Cialdi, et al. |
| 24. | 5,008,253 | Apr. 16, 1991 | Casu, et al. |

Foreign Patent Documents

| | <u>Patent No.</u> | <u>Date</u> | <u>Country</u> |
|-----|--------------------------|--------------------|-----------------------|
| 25. | 0 216 453 B1 | March 20, 1996 | Europe |
| 26. | WO 95/26735 | Oct. 12, 1995 | PCT |

Other Documents

27. Baba, Tooru, et al., "Ultrastructural Cytochemistry of Carbohydrates in Microfibrils Associated with the Amorphous Elastin in the Monkey Aorta" The Anatomical Record (1985) Vol. 213:385-391;
28. Baccarani-Contri, M., et al., "Elastin-Proteoglycans Association Revealed by Cytochemical Methods", Connective Tissue Research (1985) Vol. 13:237-249;
29. Baccarani-Contri, M., et al., "Immunocytochemical Localization of Proteoglycans Within Normal Elastin Fibers", European Journal of Cell Biology (1990) Vol. 53:305-312;
30. Cantor, J., et al. "Further Investigation of the Use of Intratracheally Administered Hyaluronic Acid to Ameliorate Elastase-Induced Emphysema", Experimental Lung Research (1997) Vol. 23:229-244;
31. Cantor, J., et al., "Aerosolized Hyaluronic Acid Decreases Alveolar Injury Induced by Human Neutrophil Elastase", P.S.E.B.M. (1998) Vol. 217:471-475;
32. Erlinger, R., "Glycosaminoglycans in Porcine Lung: An Ultrastructural Study Using Cupromeronic Blue", Cell Tissue Research (1995) Vol. 281:473-483;
33. Abstract by Ishibashi M., et al. (December 1995) "The role of interstitial hyaluronan in acute lung injury" 33 (Suppl): 225-230;
34. An English translation of Ishibashi, M., et al. (1995) "The Role of Interstitial Hyaluronan in acute Lung Injury" Japanese Journal of Thoracic Disease, 33(Suppl): 225-230;
35. The Japanese version of Ishibashi, M., et al. (1995), "The Role of Interstitial Hyaluronan in Acute Lung Injury" Japanese Journal of Thoracic Disease, 33(Suppl): 225-230;
36. Abstract by Murakami, H., et al. (July 1998) "Effect of hyaluronidase on porcine pancreatic elastase-induced lung injury" 36(7):577-584;
37. Bray, B.A., et al., "Lung Hyaluronan as Assayed with a Biotinylated Hyaluronan-Binding Protein", Exper. Lung Res. (1994) 20:317-330;
38. Cantor, J., et al., "Modulation of Airspace Enlargement in Elastase-Induced Emphysema by Intratracheal Instillment of Hyaluronidase and Hyaluronic Acid", Exper. Lung Res. (1995) 21:423-436;
39. Cantor, J., et al., "Pulmonary Air-Space Enlargement Induced by Intratracheal Instillment of Hyaluronidase and Concomitant Exposure to 60% Oxygen", Exper. Lung Res. (1993) 19:177-192;

40. Rao, N.V., et al., "Sulfated Polysaccharides Prevent Human Leukocyte Elastase-induced Acute Lung Injury and Emphysema in Hamsters", Am. Rev. Respir. Dis. (1990) 142:407-412;
41. Walsh, R.L., et al., "Heparin and Heparan Sulphate are Inhibitors of Human Leukocyte Elastase", Clin. Sci. (1991) 81:341-346;
42. Cantor, J., et al., "Synthesis of Crosslinked Elastin by a Mesothelial Cell Culture", Proceedings of the Society for Experimental Biology and Medicine, vol. 181, pp. 387-391 (1986);
43. Lafuma, C., et al., "Biosynthesis of Hyaluronic Acid, Heparan Sulfate and Structural Glycoproteins in Hamster Lung Explants during Elastase Induced Emphysema", Connective Tissue Research, vol. 13, pp. 169-179 (1985);
44. Osman, M., et al., "Cigarette Smoke Impairs Elastin Resynthesis in Lungs of Hamsters with Elastase-induced Emphysema", Am. Rev. Respir. Dis., vol. 132, pp. 640-643 (1985);
45. Campbell, E., et al., "Relative Importance of Cell-Substrate Contact and Oxidative Inactivation of Proteinase Inhibitors in Vitro", J. Clin. Invest., vol. 70, pp. 845-852 (1982);
46. Toole, B., "Glycosaminoglycans in Morphogenesis", Cell Biology of Extracellular Matrix, New York, Plenum, chapter 9, pp. 259-294;
47. Chrzanowski, P., et al., "Elastin Content of Normal and Emphysematous Lung Parenchyma", The American Journal of Medicine, vol. 69, pp. 351-359 (9/1980);
48. Moczar, M., et al., "Glycosaminoglycans in Elastase Induced Emphysema", Bull. Europ. Physiopath. Resp., vol. 16 (suppl), pp. 99-104 (1980);
49. de Belder, A., et al., "Preparation and Properties of Fluorescein-Labelled Hyaluronate", Carbohydrate Research, vol. 44, pp. 251-257 (1975);
50. Motomiya, M., et al., "Über Glykosaminoglykane bei einem Fall von Lungenemphysem", Z. Erkr. Atm., vol. 143, pp. 270-276 (1975);
51. Laurell, C.-B., et al., "The Electrophoretic α_1 -Globulin Pattern of Serum in α_1 -Antitrypsin Deficiency", Scandinav. J. Clin. & Lab. Investigation, vol. 15, pp. 132-140 (1963);
52. Bhattacharya, J., et al., "Hyaluronan affects extravascular water in lungs of unanesthetized rabbits", J. Appl. Physiol., vol. 66, pp. 2595-2598 (1989);
53. Zimmerman, M., et al., "Design and Properties of Synthetic Elastase Inhibitors", Elastin and Elastases, volume II, chapter 12, pp. 109-123;

54. Senior, R., et al., "The Pathogenesis of Emphysema", Pulmonary Diseases and Disorders, 2d ed., New York, McGraw-Hill, chapter 74, pp. 1209-1218 (1988);
55. Page, C., "Proteoglycans: The "Teflon" of the airways?", Thorax, The Journal of the British Thoracic Society, vol. 52, no. 10, pp. 924-925 (1997);
56. Pare, P., et al., "The functional consequences of airway remodelling in asthma", Damage and Remodelling in Airway Inflammation", vol. 52, no. 6, pp. 589-596 (1997);
57. Rosenbaum, D., "Hyaluronan in Radiation-Induced Lung Disease in the Rat", Radiation Research, vol. 147, pp. 585-591 (1997);
58. Akima, K., et al., "Evaluation of Antitumor Activities of Hyaluronate Binding Antitumor Drugs: Synthesis, Characterization and Antitumor Activity", Journal of Drug Targeting, vol. 4, pp. 1-8 (1996);
59. Pruimboom, I., et al., "Capsular Hyaluronic Acid-mediated Adhesion of *Pasteurella multocida* to Turkey Air Sac Macrophages", Avian Diseases, vol. 40, pp. 887-893 (1996);
60. Sköld, C., et al., "Transient increases in albumin and hyaluronan in bronchoalveolar lavage fluid after quitting smoking: possible signs of reparative mechanisms", Respiratory Medicine, vol. 90, pp. 523-529 (1996);
61. Juul, S., et al., "Hyperoxia Alone Causes Changes in Lung Proteoglycans and Hyaluronan in Neonatal Rat Pups", American Journal of Respiratory Cell and Molecular Biology, vol. 13, pp. 629-638 (1995);
62. Song, W.D., et al. "Fibronectin and Hyaluronan in Bronchoalveolar Lavage Fluid from Young Patients with Chronic Obstructive Pulmonary Diseases", Respiration, vol. 62, pp. 125-129 (1995);
63. Teder, P., et al., "Characterization of the Mechanism Involved in Bleomycin-induced Increased Hyaluronan Production in Rat Lung; American Journal of Respiratory Cell and Molecular Biology, vol. 12, pp. 181-189 (1995);
64. Aviad, A., et al., "The Molecular Weight of Therapeutic Hyaluronan (Sodium Hyaluronate): How Significant is it?", The Journal of Rheumatology, vol. 21, pp. 297-301 (1994);
65. Gandhi, R., et al., "Analysis of elastin cross-linking and the connective tissue matrix of abdominal aortic aneurysms", Surgery, vol. 115, pp. 617-620 (5/1994);
66. Juul, S., et al., "Changes in Hyaluronan Deposition during Early Respiratory Distress Syndrome in Premature Monkeys", Pediatric Research, vol. 35, no. 2, pp. 238-243 (1994);

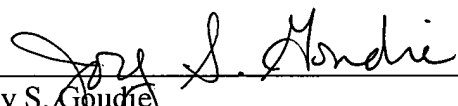
67. Townsley, M., et al., "Hyaluronan Efflux from Canine Lung with Increased Hydrostatic Pressure and Saline Loading", American Journal of Respiratory and Critical Care Medicine, vol. 150, pp. 1605-1611 (1994);
68. Goldberg, E., et al., "Prevention of Postoperative Adhesions by Precoating Tissues with Dilute Sodium Hyaluronate Solutions", Prog. Clin. Biol. Res., vol. 381, pp. 191-204 (1993);
69. Graf, J., et al., "Intra-articular treatment with hyaluronic acid in osteoarthritis of the knee joint: a controlled clinical trial versus mucopolysaccharide polysulfuric acid ester", Clinical and Experimental Rheumatology, vol. 11, pp. 367-372 (1993);
70. Leardini, G., et al., "Intra-articular treatment of knee osteoarthritis. A comparative study between hyaluronic acid and 6-methyl prednisolone acetate", Clinical and Experimental Rheumatology, vol. 9, pp. 375-381 (1991);
71. Nettelbladt, O., et al., "Alveolar accumulation of hyaluronan and alveolar cellular response in bleomycin-induced alveolitis", Eur. Respir. J., vol. 4, pp. 407-414, (1991);
72. Cantor, J., et al., "The Effect of 60% Oxygen on Air-space Enlargement and Cross-linked Elastin Synthesis in Hamsters with Elastase-induced Emphysema", Am. Rev. Respir. Dis., vol. 142, pp. 668-673 (1990);
73. Shteyngart, B., et al., "Preferential binding of lysozyme to elastic fibres in pulmonary emphysema", Thorax, vol. 53, pp. 193-196 (1998);
74. Tyrrell, D., et al., "Heparin in Inflammation: Potential Therapeutic Applications beyond Anticoagulation", Adv. Pharmacol., vol. 46, pp. 151-208 (1999);
75. Feng, W., et al., "Improved Clearability of Cystic Fibrosis Sputum with Dextran Treatment *in vitro*", Am. J. Respir. Crit. Care Med., vol. 157, pp. 710-714 (1998);
76. Barnes, P., et al., "Inflammatory Mediators of Asthma: An Update", Pharmacological Reviews, vol. 50, no. 4, pp. 515-596 (1998);
77. Cantor, J., Abstract for "Intratracheal Instillment of Hyaluronic Acid Decreases Elastase-Induced Air-Space Enlargement in Hamsters", Exper. Lung Res., vol. 19, pp. 177-192 (1993); and
78. Zhou, D., et al., (article in Chinese) "The changes in collagen contents and its clinical significance in chronic obstructive pulmonary disease", Chung Hua Chieh Ho Ho Hu His Tsa Chih, vol. 18, no. 5, pp. 301-2, 319 (10/1995).

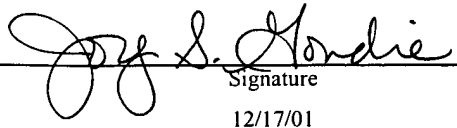
Applicants request that these documents be considered by the Examiner before issuance of the next action and made of record in this file. The Examiner is also asked to initial and return a copy of the enclosed Forms PTO-1449 to evidence such consideration.

This Information Disclosure Statement is being filed in accordance with the provisions under 37 C.F.R. §1.97(b)(3). To the best of the undersigned's knowledge, before the mailing of a first Office Action on the merits. No fee is required.

The Commissioner is hereby authorized to charge (or credit any overpayment) any fees which are due to Deposit Account No. 02-4467.

Respectfully submitted,

By: 
Joy S. Goudie
Reg. No. 48,146
BRYAN CAVE LLP
245 Park Avenue
New York, New York 10167-0034
(212) 692-1800

| |
|--|
| I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on December 17, 2001 |
| (Date of Deposit) |
| Joy S. Goudie |
| Name of applicant, assignee, or Registered Representative |
|  Signature |
| 12/17/01 |
| Date of Signature |